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10/727,096	12/02/2003	David K. Swanson	015916-304	6001

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EXAMINER

ROANE, AARON F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/727,096	<b>Applicant(s)</b> SWANSON, DAVID K.	
	<b>Examiner</b> Aaron Roane	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-12,28-35,37-40 and 43-53 is/are pending in the application.
- 4a) Of the above claim(s) 12,29 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-11,28,30-35,37-40 and 43-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/7/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11, 28, 30-35 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent claims 7 and 28 recite a tissue stimulation element or means that is too small to form a transmural lesion in myocardial tissue. Although Applicant recites various dimensions of the tissue stimulation element or means and more importantly gives some examples of operating parameters (see for example claims 31-39 and pages 24-27 of the specification), the specific recitation in the independent claims does not explicitly set forth a threshold size. Additionally, it can be appreciated by one of ordinary skill in the art that creating a transmural lesion depends on several parameters, i.e., current, duration of application, etc. and that a particular sized tissue stimulation element or means maybe used in one modality to create transmural lesion while in another modality it may be used in a manner that does not create and is incapable of creating transmural lesions.

In addition, on page 26, line 2, Applicant provides an example of a stimulation electrode that is too small to form a transmural lesion as being 0.5 mm to 2 mm in length. The examiner has pointed out that just size alone is a poor determinant of whether an electrode is capable of forming a transmural lesion. For example, Avitall (US 5,687,723) discloses a catheter having electrodes (143) that are about 2 mm long and are used to create linear lesions in cardiac tissue, see col. 7, lines 35-61 and figures 1-4 and 9. Applicant is also encouraged to review Imran (US 5,406,946, who discloses much smaller electrodes than Avitall that form lesions in cardiac tissue.

It should be clear from the noted references above, that the capability, or in capability of an electrode to form transmural lesions in cardiac tissue is dependent on not only the electrode size, but also more importantly on the current, power and duration of application. Applicant has at least hinted that other factors/parameters are important regarding the formation of transmural lesions in that Applicant has also disclosed relevant threshold current densities, see page 27, lines 12-26.

In order to provide an examination, the examiner interprets the recitation that the tissue stimulation element or means that is too small to form a transmural lesion in myocardial tissue as intended use and/or functional language.

### ***Election/Restrictions***

Applicant's election without traverse of group I, specie #8 and subspecie A in the reply filed on 6/16/2005 has been previously acknowledged. However, the response filed 5/4/2006,

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Applicant added new claims 47-53. It is noted that claim 53 is directed to a non-elected specie/subspecie and therefore has been withdrawn by the examiner.

The examiner will examine claims 7-11, 28, 30-35, 37-40 and 43-52.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 9-11, 28, 30, 40, 43, 45-47, 49 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundback (US 4,736,749).

Regarding claim 7, 9-11, 28, 43, 45-47, 49, 50 and 52, Lundback discloses a surgical apparatus comprising a tube (8) defining a proximal region and a distal region; a cup-shaped suction device (1 and 2 collectively) associated with the distal region of the tube, wherein part of the cup-shaped suction device is flexible (1), a tissue stimulation electrode (the tissue contacting side of 30); a source of stimulation energy (“electrical power source not shown” see col. 3, lines 3-12) connected to the stimulation electrode; and a suction source (see col. 3, lines 26-29), see col. 3 and 4 and figures 1-4.

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Regarding claims 30 and 40, Lundback discloses an electrode size for the stimulation electrode that does not form a lesion of any kind at all, see col. 3 and 4 and figures 1-4.

Regarding claim 51, Lundback further disclose a suction device that defines an inner surface and the signal line extends along the inner surface and through the opening that is in fluid communication with the suction lumen, see figures 1-3.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundback (US 4,736,749) in view of Samson (US 6,185,442).

Regarding claims 8, 44 and 48, Lundback discloses the claimed invention except for explicitly reciting that the suction tube is flexible. Samson disclose a suction electrode device comprising a suction (10) and an electrode (16) and teach the use of connecting the suction cup (10) to the pressure manipulator (14) via a bendable hose/tubing (15) in order to provide suction or vacuum pressure to the cup and to facilitate the comfort and

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versatile positioning during use, see col. 3 and 4 and figures 1-3. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Lundback, as taught by Samson, to use a bendable hose/tubing in order to connect the suction cup to the pressure manipulator and to facilitate comfort and versatile positioning during use.

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Claims 31-33 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundback (US 4,736,749) in view of Samson (US 4,685,466).

Regarding claims 31-33 and 37-39, Lundback discloses the claimed invention except for explicitly reciting that the stimulation electrode defines a perimeter of about 1.5 mm to 3mm, a thickness of about 0.01 mm and/or a diameter of about 0.5 mm to 1.0 mm. Rau discloses a stimulation suction electrode and teaches providing the electrode in a needle configuration (1) in order to provide fixation without electrode paste or jelly and to reduce skin resistance, see col. 3, lines 1-15, col. 4, lines 29-49 and figures 4-6.

The needle electrode of Rau provides all of the recited dimensions of the claimed invention. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Lundback, as taught by Rau, to provide the suction electrode with a needle electrode in order to provide fixation without electrode paste or jelly and to reduce skin resistance.

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Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundback (US 4,736,749) in view of Colliou et al. (US 7,020,531).

Regarding claims 34 and 35, Lundback discloses the claimed invention except for explicitly reciting that the source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10 mA and two stimulation pulses per second. Colliou et al. disclose a stimulating suction electrode device and teach providing the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100  $\mu$ sec to 20 msec in order to provide electrical stimulation, see col. 23, line 46 through col. 24, line 6 and figures 16A and 16B. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Lundback, as taught by Colliou et al., to provide the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100  $\mu$ sec to 20 msec in order to provide electrical stimulation to tissue.

### ***Response to Arguments***

Applicant's arguments directed to the 112 1<sup>st</sup> rejections filed 5/4/2006 have been fully considered but they are not persuasive. The examiner has provided further evidence coming from a) Applicant's disclosure and b) prior art that the recitation of "a tissue stimulation element that



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is too small to form a transmural lesion in myocardial tissue on the suction device” is lacking the enablement requirement. Applicant’s request of an affidavit is moot due to the evidence/support for the 112 1<sup>st</sup> enablement rejection in Applicant’s disclosure and the prior art.

Applicant's arguments with respect to claims 7-11, 28-35, 37-40, 43-52 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.R. *A.R.*  
July 10, 2006

*Roy D. Gibson*  
ROY D. GIBSON  
PRIMARY EXAMINER